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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHYI-CHENG CHEN and BRUNO LEUENBERGER

Appeal 2012-008653
Application 09/726,880
Technology Center 1600

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims directed to a vitamin powder composition. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification describes a powder composition of one or more fat-soluble vitamins, such as vitamin E, A, K, and D_3 and relevant esters. (Spec. 1, 9-10.) Droplets of the vitamins are dispersed in a matrix of a natural polysaccharide gum (e.g., gum arabic), protein (e.g., gelatine), or mixture of such gums or proteins, having an emulsifying capacity (*id.* at 4, 8, 9). The droplets have an average diameter of about 80 to 120 nm. As stated in the Specification, the powder "composition may contain only vitamin and matrix components in percentages that add up to 100%" (*id.* at 11). Alternatively, the powder may comprise additional components, such as "weighting agents" and/or "emulsifiers and emulsion stabilizers," which "may be used to stabilize the emulsion droplets" (*id.* at 17). The Specification describes adding powders to beverages, but also states that "powder compositions of this invention may also be added to cosmetics" (*id.* at 20).

Claims 3-14, 17, 28-31, and 33-36 are on appeal. Independent claims 36 and 29 are representative, and read as follows (emphasis added):

> 36. A powder composition *consisting of* at least one fat-soluble vitamin *dispersed in a matrix consisting of an emulsion-forming composition selected from* the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, *wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 80 to about 120 nanometers (nm)* and wherein the fat-soluble vitamin is present in the powder composition in the amount of from about 10% to about 30% by weight and wherein the composition has a moisture content of about 1 to 4% by weight.

29. A powder composition *consisting of* at least one fat-soluble vitamin *dispersed in a matrix of an emulsion-forming composition selected from* the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets, wherein the powder composition is produced by a process comprising:

(a) …;

(b) …;

(c) emulsifying the crude emulsion at a temperature of from about 5° C to about 75° C at a pressure of from about 10,000 psi (about 680 bar) to about 60,000 psi (about 4080 bar), *to obtain an emulsion in which the droplets have an average diameter of about 80 to about 120 nm*; and

(d) ….

The claims stand rejected as follows:

• claims 3-14, 17, 28-31, and 33-36 under 35 U.S.C. § 103(a) as obvious over either Auweter[1] in view of Lorant,[2] or Auweter and Stein[3] in view of Lorant; and

• claim 36 under 35 U.S.C. § 103(a) as obvious over either Auweter in view of Lorant and Cannalonga,[4] or Auweter and Stein in view of Lorant and Cannalonga.

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[1] Auweter (U.S. Pat. No. 5,968,251, issued Oct. 19, 1999).
[2] Lorant (U.S. Pat. No. 5,952,395, issued Sep. 14, 1999).
[3] Stein et al. (EP 0 937 412 A1, published Aug. 25, 1999).
[4] Cannalonga (U.S. Pat. No. 2,756,177, issued Jul. 24, 1956).

Issue

Does the Examiner establish that it would have been prima facie obvious to prepare a powder composition consisting of fat-soluble vitamin droplets dispersed in a matrix consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof, where the vitamin droplets have an average diameter of about 80 to about 120 nm, in view of cited references?

Principles of Law

The Examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). If the Examiner fails to establish a prima facie case of unpatentability in the first instance, the rejection is improper and must be reversed. *Id.*; *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).

The claim phrase "consisting of" is a "closed" transition phrase that is "understood to exclude any elements, steps, or ingredients not specified in the claim." *AFG Indus., Inc. v. Cardinal IG Co.*, 239 F.3d 1239, 1244–45 (Fed. Cir. 2001); *see also Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32 (Fed. Cir. 2004) (holding that a bone repair kit "consisting of" claimed chemicals was infringed by a bone repair kit including a spatula in addition to the claimed chemicals because the presence of the spatula was unrelated to the claimed invention); MPEP 2111.03 ("Transitional Phrases").

Claim 36

As noted above, independent claim 36 (and therefore dependent claims 3-14, 17, and 28) recite "a powder composition *consisting of* at least one fat-soluble vitamin *dispersed in a matrix consisting of an emulsion-forming composition selected from* the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof …." (Claim 36 (emphasis added).) In other words, the powder composition includes one or more fat-soluble vitamins dispersed in a matrix that is a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof. By virtue of the "consisting of" language, however, the recited powder composition may not include other components relevant to the powder, such as "emulsifiers and emulsion stabilizers … used to stabilize the emulsion droplets" (Spec. 17), that are not natural polysaccharide gums, proteins, or mixtures of one or both. *AFG*, 239 F.3d at 1244–45; *see also Norian*, 363 F.3d at 1331 (stating that "while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention").

The Examiner finds that Auweter and/or Stein describes the powder composition of claim 36, except that neither reference discloses the recited solid droplet diameter of about 80 to about 120 nm (Ans. 5). Specifically, the Examiner notes that "Auweter teaches particles of 200 nm size (col. 3, L 51-56)," and that Stein "does not readily envisage the claimed particle size of 80-120 nm" (*id*). Likewise, the Examiner does not indicate that Cannalonga describes smaller diameter droplets, or otherwise propose that

this reference teaches or suggest anything about fat-soluble vitamin droplet diameter size (Ans. 9, 16).

Regarding the smaller droplet diameter, the Examiner states that "Lorant teaches gelled ultrafine oil-in-water emulsions having a particle size of 50 nm to 1000 nm (abstract)," as well as "nanoparticle sizes in the range of 30-200 nm (col. 4, l 34-43)" (*id.* at 5)[5] The Examiner finds that "Lorant teaches that the smaller particle size, lesser the surface tension and higher the stability (see col. 1, l 26-32)," and that "reducing the particle size of the oily phase can reduces the need for high concentrations of emulsifying agents and suggests a particle size of 50-1000 nm" (*id.* at 6, 14, 16). Thus, according to the Examiner, it would have been obvious for one of ordinary skill to prepare the vitamin powders of Auweter and/or Stein having droplets with a diameter as low as 30-200 nm (*id.* at 6).

Appellants assert, among other things, that "Auweter and Stein do not suggest formulations having the claimed droplet size having an average diameter of about 80 to about 120 nm, which … have optical clarity and which appear transparent and/or translucent in an otherwise clear solution" (App. Br. 10). Appellants refer to a declaration by Hermann Stein (an inventor of the Stein reference), where Mr. Stein states that "[d]uring the research that led to the invention disclosed in Stein, my co-inventors and I, using the knowledge available at the time, attempted to produce the smallest possible particle size," and "[a]s Example 5 shows, at the time, at best we could produce particle sizes of about 196 nm." (*Id.* at 13 (citing Stein

[5] We assume "(col. 4, l 34-43)" in the last line of page 5 of the Answer intends to refer to Lorant, col. 6, ll. 34-43.

Declaration (submitted with Response dated March 28, 2005), ¶¶ 6-7).) Appellants also submit declaration evidence supporting the statement that "the processes of Stein and Auweter would produce carotenoid particle sizes in a comparable range of about 200 nm," not 80-120 nm. (App. Br. 15 (citing Leuenberger Declaration (submitted November 12, 2009), ¶ 30; *see also* ¶¶ 27-29).) The Examiner does not dispute this evidence, but relies on Lorant for teaching one skilled in the art to make and use smaller diameter droplets.

Appellants correctly point out, however, that Lorant teaches "that ultrafine specific oil in water emulsions in which the mean size of the globules forming in the fatty phase is between 50 and 1000 nm is still fragile and still poses a number of stability problems" (Reply Br. 6). As stated by Appellants, "[t]o overcome these disadvantages, Lorant is directed to a new class of thickening or gelling polymers which make it possible to produce emulsions obtained by phase inversion, which are stable" (*id.* (citing Lorant, col. 2, ll. 36-38)). Appellants note that Lorant discloses the use of a specific polymer, i.e., a cross-linked poly(2-acrylamido-2-methylpropanesulphonic acid) for stabilizing the emulsions (*id.* (citing Lorant, col. 3, ll. 10-11)).

We likewise find that Lorant teaches the use of a cross-linked polymer for the purpose of producing "' ultrafine' specific O/W emulsions" that "are stable in all the viscosity ranges" (Lorant, col. 1, 42-49; col. 2, ll. 36-44). The Examiner appears to acknowledge this point when stating that "Lorant teaches that ultrafine particle oil-in-water emulsion pose stability problems, become extremely fluid, require specific oils to avoid separation and also bluish in appearance," and "[t]herefore in order to overcome the problems,

Lorant suggests adding a gelling polymer to the aqueous phase and further suggests incorporating cosmetically active agents (see entire col. 2)" (Ans. 5). Nonetheless, the Examiner emphasizes that "Lorant teaches that the smaller particle size, lesser the surface tension and higher the stability (see col. 1, l 26-32)" (*id.* at 6).

In this regard, we see that Lorant states in column 1 that "[t]o solve the problems of stability of conventional O/W emulsions *it has been proposed to produce so-called 'ultrafine' specific O/W emulsions* in which the mean size of the globules forming the fatty phase is within well-determined limits, namely between 50 and 1000 nm," which may be obtained using known techniques (Lorant, col. 1, ll. 42-66) (emphasis added).

Immediately thereafter in column 2, however, Lorant further explains that "[e]mulsions of these types are fragile and still pose a number of stability problems." (Lorant, col. 2, ll. 1-35). Such problems include that "the production of ultrafine emulsions makes it necessary to employ very specific oils and emulsifying agents in specified conditions," and that "the extreme fluidity of these emulsions limits their use to a very restricted viscosity range and to very specific cosmetic or dermatological fields" (*id.* at ll. 6-13).

The overall point of Lorant's teachings is to solve such stability problems. In this regard, Lorant states that they "surprisingly discovered a new class of thickening or gelling polymers which make it possible to produce emulsions obtained by phase inversion, which are stable in all the viscosity ranges." (*Id.* at ll. 36-39.) Lorant then describes the specific

polymers in columns 3-16, i.e., crosslinked poly(2-acrylamido-2-methylpropanesulphonic acid) polymers.

Thus, while we agree with the Examiner that one skilled in the art might have been motivated to prepare a vitamin powder of Auweter, Stein, and/or Cannalonga having vitamin droplets with a diameter as low as 30-200 in light of Lorant, Lorant teaches or suggests also including a specific crosslinked polymer for the purpose of overcoming stability problems associated with the "ultrafine" powder. Moreover, in light of the described stability problems, Lorant as a whole teaches away from preparing "ultrafine" O/W emulsions in the absence of the specific crosslinked polymer, i.e., poly(2-acrylamido-2-methylpropanesulphonic acid) polymer, described in Lorant (*see* cols. 3-16).

The Examiner's Answer does not sufficiently address these points. In addition, the Answer does not address the "consisting of" language in claim 36, or that such language precludes including a relevant component that is not a fat-soluble vitamin, a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof, in the recited powder. Likewise, the Examiner does not assert that "natural polysaccharide gum" or "protein" in claim 36 encompasses a stabilizing crosslinked polymer disclosed in Lorant, or that Lorant suggests the use of a natural polysaccharide gum, protein, or mixtures thereof, to solve the stability problems described in Lorant when making and using "ultrafine" particles. Thus, the Examiner does not establish by a preponderance of the evidence that claim 36 (and corresponding dependent claims) are obvious over Auweter and/or Stein in view of Lorant and/or Cannalonga.

Claim 29

Independent claim 29 (and therefore dependent claims 30-35) recite a "powder composition *consisting of at least one fat-soluble vitamin* dispersed in *a matrix of an emulsion-forming composition selected from the group consisting of* a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof." (Claim 29 (emphasis added).) Based on the italicized language in the claim language quoted above, and in light of the Specification, we interpret claim 29 similarly to claim 36 in that the recited powder composition excludes any relevant component that is not a fat-soluble vitamin, a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof.

Moreover, (c) in claim 29 (a product-by-process element) recites emulsifying at certain temperatures and pressures "to obtain an emulsion in which the droplets have an average diameter of about 80 to about 120 nm." In other words, the powder composition of claim 29 comprises droplets having a diameter of about 80-120 nm. As such, the analysis above regarding claim 36 applies to claim 29 as well.

Again, the Examiner has not established by a preponderance of the evidence that an ordinary artisan would have used any technique to prepare any "ultrafine" droplets unless the composition in question included a stabilizing crosslinked polymer as described in Lorant. The Examiner does not establish that one skilled in the art would have been motivated in light of Lorant and/or other cited references to prepare the powdered composition of claim 29 comprising vitamin droplets having an average diameter of 80-120

nm, where the composition excludes stabilizers that are not natural polysaccharide gums, proteins or mixtures thereof (as recited in claim 29). Moreover, the Examiner does not suggest that relevant polymers disclosed in Lorant qualify as a natural gum and/or protein. Thus, the Examiner does not establish by a preponderance of the evidence that claim 29 (and corresponding dependent claims) are obvious over Auweter and/or Stein in view of Lorant.

Conclusion of Law

The Examiner does not establish that it would have been prima facie obvious to prepare a powder composition consisting of fat-soluble vitamin droplets dispersed in a matrix consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof, where the vitamin droplets have an average diameter of about 80 to about 120 nm, in view of cited references.

SUMMARY

We reverse the obviousness rejection of claims 3-14, 17, 28-31, and 33-36 over either Auweter in view of Lorant, or Auweter and Stein in view of Lorant. We also reverse the obviousness rejection of claim 36 over either Auweter in view of Lorant and Cannalonga, or Auweter and Stein in view of Lorant and Cannalonga.

REVERSED

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